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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,385	11/23/2001	Koji Yanai	2001-1611	4331

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EXAMINER

HUTSON, RICHARD G

ART UNIT PAPER NUMBER

1652

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,385

Applicant(s)

YANAI ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/13/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-56 is/are pending in the application.
- 4a) Of the above claim(s) 55 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/142,623.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants cancellation of claims 1-52 and the addition of new claims 53-56 in the papers of 9/8/2003 and 11/13/2003, is acknowledged. Claims 53-56 are still at issue and are present for examination.

Applicants' arguments filed on 9/8/2003 and 11/13/2003, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Applicants statement regarding that newly added claims 55 and 56 correspond to previous non-elected claims 26 and 50 are acknowledged, however, applicants are reminded that claims 55 and 56 are not subject to rejoinder until the time at which claims 53 and 54 are found allowable.

Claims 55 and 56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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This rejection was stated in the previous office action as it applied to previous claims 22 and 24. In response to this rejection applicants have canceled claims 22 and 24 and added new claims 53 and 54 drawn to the same subject matter and applicants traverse the rejection as it applies to these newly added claims.

Applicants submit that the new claims are in compliance with 35 USC 112, first paragraph because a skilled artisan would readily recognize from the teachings of the specification that the applicants was in possession of the claimed invention, an *Aspergillus* mold fungus, with the described required property.

Applicants argument is not found persuasive because while the skilled artisan might recognize that applicants were in possession of an *Aspergillus* mold fungus which is missing all or a part of a β -fructofuranosidase gene on its chromosome DNA, the skilled artisan would not recognize that the taught *Aspergillus* mold fungus has "no detectable β -fructofuranosidase activity". While the β -fructofuranosidase activity of the taught *Aspergillus* mold fungus may be significantly reduced and almost nothing relative to the proper controls, it is not believed that this *Aspergillus* mold fungus would have "no detectable activity" (See also previous 112 second paragraph rejection and applicants response).

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

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Claims 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mutant *Aspergillus niger* in which its β -fructofuranosidase gene has been deleted, does not reasonably provide enablement for a *Aspergillus niger* with no β -fructofuranosidase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claims 22 and 24. In response to this rejection applicants have canceled claims 22 and 24 and added new claims 53 and 54 drawn to the same subject matter and applicants traverse the rejection as it applies to these newly added claims.

Applicants traverse this rejection in combination with the above 112 first paragraph rejection based on a lack of enablement on the basis that applicants the specification fully enables one of skill in the art to make and use the invention commensurate in scope with the claims.

As above, Applicants argument is not found persuasive because while the skilled artisan might recognize as enabled an *Aspergillus* mold fungus which is missing all or a part of a β -fructofuranosidase gene on its chromosome DNA, the skilled artisan would not recognize as enabled an *Aspergillus* mold fungus having "no detectable β -fructofuranosidase activity". While the β -fructofuranosidase activity of the taught *Aspergillus* mold fungus may be significantly reduced and almost nothing relative to the proper controls, it is not believed that this *Aspergillus* mold fungus would have "no detectable activity" (See also previous 112 second paragraph rejection and applicants

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response). Thus such a limitation of the claimed *Aspergillus* mold fungus is not enabled.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any *Aspergillus niger* with no β -fructofuranosidase activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those mutants having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 22 and 24 are under 35 U.S.C. 102(b) as anticipated by Nakamura et al. (Journal of Fermentation and Bioengineering, Vol 78, No. 2, 134-139, 1994, See IDS, Ref AL) is hereby withdrawn in light of the cancellation of claims 22 and 24 and applicants traversal.

This rejection was stated in the previous office action as it applied to previous claims 22 and 24. In response to this rejection applicants have canceled claims 22 and 24 and added new claims 53 and 54 drawn to the same subject matter and applicants traverse the rejection as it applies to these newly added claims.

This rejection is not applied to claim 53 in light of applicants traversal of the previous rejection. Specifically applicants argue that the claimed mutant has "no detectable β -fructofuranosidase activity" and "mutant 817 of the cited reference still has invertase (β -fructofuranosidase) activity, according to Table 1 on page 137 of the reference".

13/2003

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
1/24/2004